



Patient Information Sheet

Ziprasidone (marketed at Geodon)

This is a summary of the most important information about Geodon. For details, talk to your healthcare professional.

FDA ALERT [04/2005] – Geodon is a type of medicine called an atypical antipsychotic. FDA has found that older patients treated with atypical antipsychotics for dementia had a higher chance for death than patients who did not take the medicine. This is not an approved use.

FDA has asked the companies that make these medicines to change their labels to include this important information.

This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What Is Geodon?

- Geodon is an antipsychotic medicine. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs, or unusual suspiciousness.
- Geodon is used to treat mixed or manic episodes in adults who have a condition called Bipolar I disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

Who Should Not Take Geodon?

Geodon can increase your chance of an abnormal heart rhythm (the way your heart beats) if you have certain heart conditions or take certain medicines. Therefore do not take Geodon if you have the following heart conditions:

- long QT syndrome (a specific heart rhythm problem)
- a recent heart attack
- severe heart failure
- certain irregularities of heart rhythm (discuss the specifics with your doctor)

What Are The Risks?

The following are the major potential risks and side effects of Geodon therapy. However, this list is not complete.

Geodon may cause dangerous problems with your heart rhythm (the way your heart beats). Call your healthcare professional right away if you:

- faint or lose consciousness
- feel a change in the way your heart normally beats (palpitations)

Geodon and other antipsychotic medications can cause serious problems such as:

- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD).** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- **Other serious side effects** with Geodon may include low blood pressure seen as dizziness, increased heart beat and possibly fainting, seizures, persistent erection), increase or decrease in body temperature, and difficulty swallowing.
- **The most common side effects** include feeling unusually tired or sleepy, nausea or upset stomach, constipation, dizziness, restlessness, diarrhea, rash, increased cough / runny nose.

What Should I Tell My Healthcare Professional?

Before you start taking Geodon, tell your healthcare professional if you:

- have or had heart problems
- have or had seizures
- have or had diabetes or increased blood sugar
- are trying to become pregnant, are already pregnant, or are breast-feeding.
- have or had liver problems
- drink alcohol

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Geodon review all medications that you are taking with your healthcare professional, including those that you take without a prescription.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following:

- dofetilide
- sotalol
- quinidine
- certain medicines to control the way your heart beats





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- mesoridazine
- thioridazine
- chlorpromazine
- droperidol
- pimozide
- sparflaxacin
- gatifloxacin
- moxifloxacin
- halofantrine
- mefloquine
- pentamidine
- levomethadyl acetate
- dolasetron mesylate
- probucol
- certain medicines to treat high blood pressure
- tacrolimus

Avoid drinking alcohol while taking Geodon.

medicines that cause this kind of change have sometimes caused rare dangerous heart rhythm problems. Because of this possible risk, Geodon should be used only after your doctor has considered this risk for Geodon against the risks and benefits of other medicines available for treating schizophrenia.

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Geodon, especially when you first start taking this medicine or when the dose is increased.
- Geodon may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Geodon affects you.
- It is important to avoid overheating and dehydration while taking Geodon. Geodon may make it harder to lower your body temperature.

Is There Anything Else I Need to Know?

- Geodon may have a higher risk of heart problems than some other medicines that are used to treat schizophrenia because it may change the way the electrical current in the heart works. We do not know whether this will be harmful, but some other

